UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

WILLIAM HOFER AND KAY HOFER, Plaintiffs, v. WRIGHT MEDICAL TECHNOLOGY, INC., a Delaware corporation, and DOES 1-10, inclusive, Defendant.	Case No.: 3:18-cv-01991-AJB-BLM **ORDER GRANTING DEFENDANT'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT** **(Doc. No. 17)**

Presently before the Court is Defendant Wright Medical Technology, Inc.'s ("Defendant") motion to dismiss Plaintiffs William and Kay Hofer's ("Plaintiffs") first amended complaint. (Doc. No. 17.) Plaintiffs oppose the motion. (Doc. No. 19.) For the reasons set forth more clearly below, the Court **GRANTS** Defendant's motion to dismiss.

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I. BACKGROUND[1]

In late 1999, Defendant purchased a manufacturer of artificial hip systems, which were designed starting in 1985. (Doc. No. 14 ¶ 12.) In or about 2000, Defendant made a design change to the original artificial hip system. (*Id*. ¶ 33.) In late 2000, Defendant received permission from the United States Food and Drug Administration ("FDA") to distribute one model ("PROFEMUR 'R'") of its artificial hip systems. (*Id*. ¶ 13). Sometime after this, Defendant began to manufacture, market, and distribute various additional products, including the PROFEMUR "Plasma Z" hip system ("PROFEMUR 'Z'") that had yet to be considered or cleared by the FDA. (*Id*. ¶¶ 14, 15, 31).

From 2002 to 2005, Defendant made representations through various marketing materials that its PROFEMUR hip systems were "designed in 1985" and implanted in 50,000 patients without any clinical failures. (*Id*. ¶ 32). Marketing also guaranteed "structural reliability" and "absence of fretting corrosion." (*Id*. ¶ 32).

"Designed in 1985" references the original design that existed prior to the 2000 design change. (*Id*. ¶ 35.) Additionally, Defendant was aware of clinical failures in the original design and knew the root cause of those failures to be fretting and corrosion. (*Id*. ¶¶ 36, 37.)

In 2002, Defendant sent a marketing letter to sale representatives identifying fretting and corrosion as barriers to selling their hip systems to surgeons. (*Id*. ¶ 38.) The letter instructed representatives to tell surgeons that the systems had been implanted 50,000 times without any clinical failures. (*Id*. ¶ 39.)

In 2008, Plaintiff William Hofer had hip arthroplasty, at which time he had a variation of Defendant's products, including the PROFEMUR "Z," implanted by Dr. Jeffrey Marxen. (*Id*. ¶¶ 67, 68.) In deciding to implant PROFEMUR "Z," Plaintiffs allege

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[1] The following facts are taken from Plaintiffs' First Amended Complaint, (Doc. No. 14), and are construed as true for the limited purpose of resolving the instant motion. *See Brown v. Elec. Arts, Inc.*, 724 F.3d 1235, 1247 (9th Cir. 2013).

Dr. Marxen relied upon Defendant's representative's depictions that PROFEMUR "Z" was FDA cleared and had a good clinical history. (*Id*. ¶¶ 40, 41.)

In 2010, the FDA became aware that the PROFEMUR "Z" was being sold and implanted, and notified Defendant to submit for clearance and cease marketing the system. (*Id*. ¶ 25.) The FDA later denied the application to market PROFEMUR "Z" due to poor clinical history. (*Id*. ¶¶ 25, 26.)

Plaintiffs allege that in December 2016, Mr. Hofer's PROFEMUR hip system failed, breaking into pieces. (*Id*. ¶ 71.) Subsequently, Mr. Hofer had the hip system surgically removed. (*Id*. ¶ 74.)

Plaintiffs allege that Defendant's PROFEMUR products implanted in Mr. Hofer were inappropriately advertised and unreasonably dangerous for the intended use. (*Id*. ¶¶ 92, 126.) On October 4, 2018, Plaintiffs filed their first amended complaint. (Doc. No. 14.) In the complaint, Plaintiffs allege (1) strict products liability – failure to warn; (2) negligence; (3) negligent misrepresentation; and (4) loss of consortium. (*See generally id*.)

II. LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a plaintiff's complaint and allows a court to dismiss a complaint upon a finding that the plaintiff has failed to state a claim upon which relief may be granted. *See Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). "[A] court may dismiss a complaint as a matter of law for (1) lack of a cognizable legal theory or (2) insufficient facts under a cognizable legal claim." *SmileCare Dental Grp. v. Delta Dental Plan of Cal.*, 88 F.3d 780, 783 (9th Cir. 1996) (citation and internal quotation marks omitted). However, a complaint will survive a motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In making this determination, a court reviews the contents of the complaint, accepting all factual allegations as true, and drawing all reasonable inferences in favor of the nonmoving party. *Cedars-Sinai Med. Ctr. v. Nat'l League of Postmasters of U.S.*, 497 F.3d 972, 975 (9th Cir. 2007).

Notwithstanding this deference, the reviewing court need not accept "legal conclusions" as true. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). It is also improper for a court to assume "the [plaintiff] can prove facts that [he or she] has not alleged." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

III. DISCUSSION

Defendant seeks dismissal only of Plaintiffs' third claim for negligent misrepresentation on the grounds that the claim fails to satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b). (Doc. No. 17-1 at 1.)

A. Application of Heightened Pleading to Negligent Misrepresentation Claims

Plaintiffs assert that the heightened pleading standard of Rule 9(b) may not apply to a negligent misrepresentation claim as it differs from one of fraud and fraud is not included in the claim's elements. (Doc. No. 19 at 4.) Although the Ninth Circuit has not decided this issue, this Court has decided: "a claim for negligent misrepresentation must meet the particularity requirement of Rule 9(b)." *Moorer v. Stemgenex Med. Grp., Inc.*, No. 16-CV-2816-AJB-NLS, 2017 WL 1281882, at *9 (S.D. Cal. Apr. 6, 2017); *see Monreal v. GMAC Mortg.*, LLC, 948 F. Supp. 2d 1069, 1078 (S.D. Cal. 2013); *Chan v. Chancelor*, No. 09-CV-1839-AJB-CAB, 2011 WL 5914263, at *5 (S.D. Cal. Nov. 28, 2011); *see also Giglio v. Monsanto Co.*, No. 15-CV-2279-BTM-NLS, 2016 WL 1722859, at *4 (S.D. Cal. Apr. 29, 2016) ("This court falls within the majority of the district courts in California that consider negligent misrepresentation a species of fraud and apply Rule 9(b)."). Therefore, the Rule 9(b) pleading standard applies to Plaintiffs' claim of negligent misrepresentation. Rule 9(b) requires plaintiffs to "state with particularity the circumstances constituting fraud or mistake." To satisfy this standard, plaintiffs must identify "the time, place, and content of [the] alleged misrepresentation[s]," as well as the "circumstances indicating falseness" or "manner in which the representations at issue were false and misleading." *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1547–48 (9th Cir. 1994), *superseded by statute on other*

grounds as stated in SEC v. Todd, 642 F.3d 1207 (9th Cir. 2011) (internal quotation marks and modifications omitted).

B. Plaintiffs Do Not Satisfy the Pleading Standards for Rule 9(b)

Defendant argues that Plaintiff has failed to plead a negligent misrepresentation claim. (Doc. No. 17-1 at 4.) Negligent misrepresentation requires (1) a misrepresentation of a material fact, (2) which is made without reasonable grounds for believing it to be true, (3) with the intent to induce reliance on the misrepresented fact, (4) that justifiable reliance occurs, and (5) resulting damage. *See Ragland v. U.S. Bank Nat'l Ass'n*, 209 Cal. App. 4th 182, 196 (Cal. Ct. App. 2012). In evaluating whether Plaintiffs' third claim for relief satisfies the heightened standard of Rule 9(b), this Court finds Plaintiffs have not met the requirements, as Plaintiffs have failed to provide the factual particularities regarding the "who, what, when, and how" of a plausible claim for negligent misrepresentation. *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124–25 (9th Cir. 2009) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (quotations omitted)).

In their complaint, Plaintiffs state that various marketing and promotional materials published and distributed by Defendant were made available to Defendant's sales representatives and distributors, surgeons, patients and the general public. (Doc. No. 14 ¶ 32.) Plaintiffs' complaint contains a statement from the Wright Medical Technical Monograph MH688-102 © 2004. *(Id.)* The following is the only specific statement Plaintiff alleges in their First Amended Complaint from the various marketing and promotional materials:

> The modular neck used with the Profemur Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur Hip. None of the necks has experienced a clinical failure since their inception.
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> …

> The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and the femoral implant guarantees:
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> - Structural reliability
> - Absence of significant micromovement
> - Absence of fretting corrosion

(*Id.*)

However, Plaintiffs allege only that Dr. Marxen relied upon the representations that the PROFEMUR "Z" was properly cleared by the FDA and that it had a good clinical history. (*Id.* ¶ 40.) Plaintiffs do not allege any specific misrepresentation that PROFEMUR "Z" had been cleared by the FDA. Further, it is unknown if Dr. Marxen or Plaintiffs relied upon the only specific misrepresentation quoted in Plaintiff's complaint. Plaintiffs have failed to allege who made any of these representations, when and where any of the representations were made, and how they were made. Plaintiffs do not allege whether Plaintiffs or Dr. Marxen were even aware of these statements, whether Plaintiffs or Dr. Marxen relied upon written or verbal representations, or how the alleged misrepresentations affected Dr. Marxen's decision regarding his selection of the device. Accordingly, Plaintiffs have failed to satisfy the heightened pleading standard of Rule 9(b).

IV. CONCLUSION

For the reasons stated above, the Court **GRANTS** Defendant's motion to dismiss with leave to amend. (Doc. No. 17.) The Court **GRANTS** Plaintiffs **twenty-one (21) days** from the date of this Order to file a second amended complaint curing the deficiencies noted herein.

IT IS SO ORDERED.

Dated: August 20, 2019

Hon. Anthony J. Battaglia
United States District Judge